Evolution of the IMPACT Evidence Library Methods – What We Have Learned

Human Research Program
Exploration Medical Capability Element

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Agenda

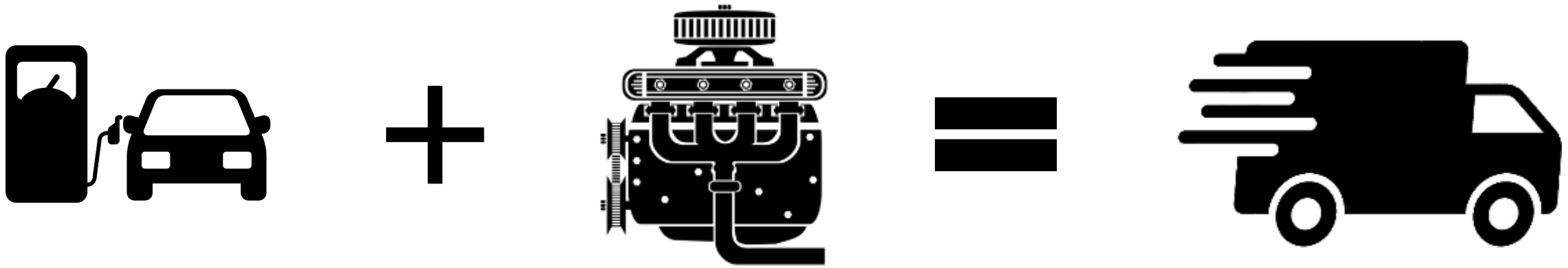
- What is IMPACT?
- Role of Evidence Library
- Outcomes from Evidence Library
- Refinements
- Challenges & Lessons Learned

What is IMPACT v1.0?

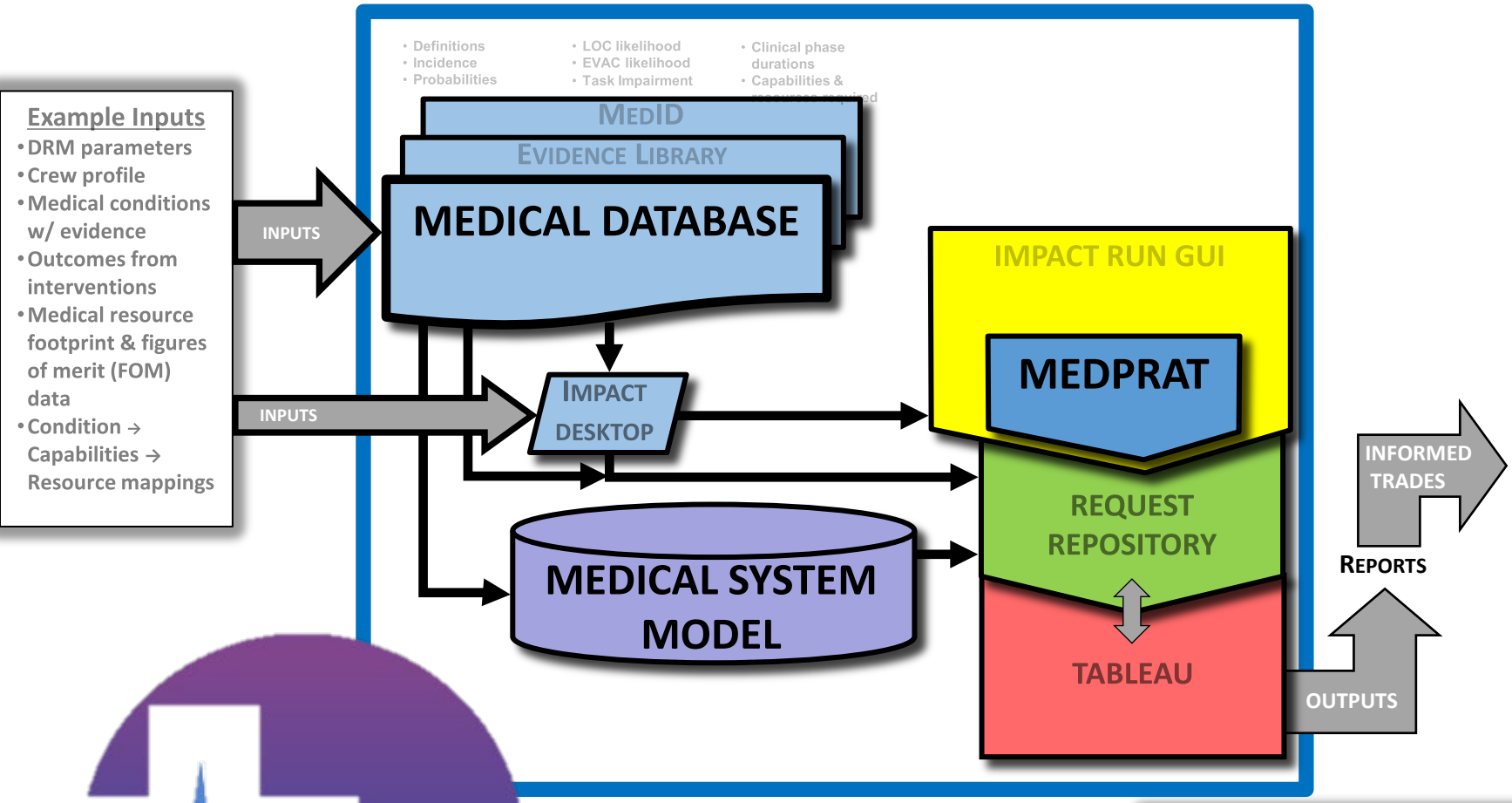
Informing **M**ission **P**lanning via **A**nalysis of **C**omplex **T**radespaces

- Tradespace analysis tool suite to inform an exploration medical system
- Successor to IMM
- Transition to Operations (TTO) FY23

Evidence Library + MEDPRAT = IMPACT



IMPACT v1.0



IMPACT v1.0

- Multi-component medical planning system
- Empowers complex layered analysis of multivariate internal & external trade space issues
- Informs key operational decisions for customers:

EXTERNAL
- HSRB
- SD
- ARTEMIS
- ORION
- GATEWAY

INTERNAL
- IMPACT TEAM

IMPACT

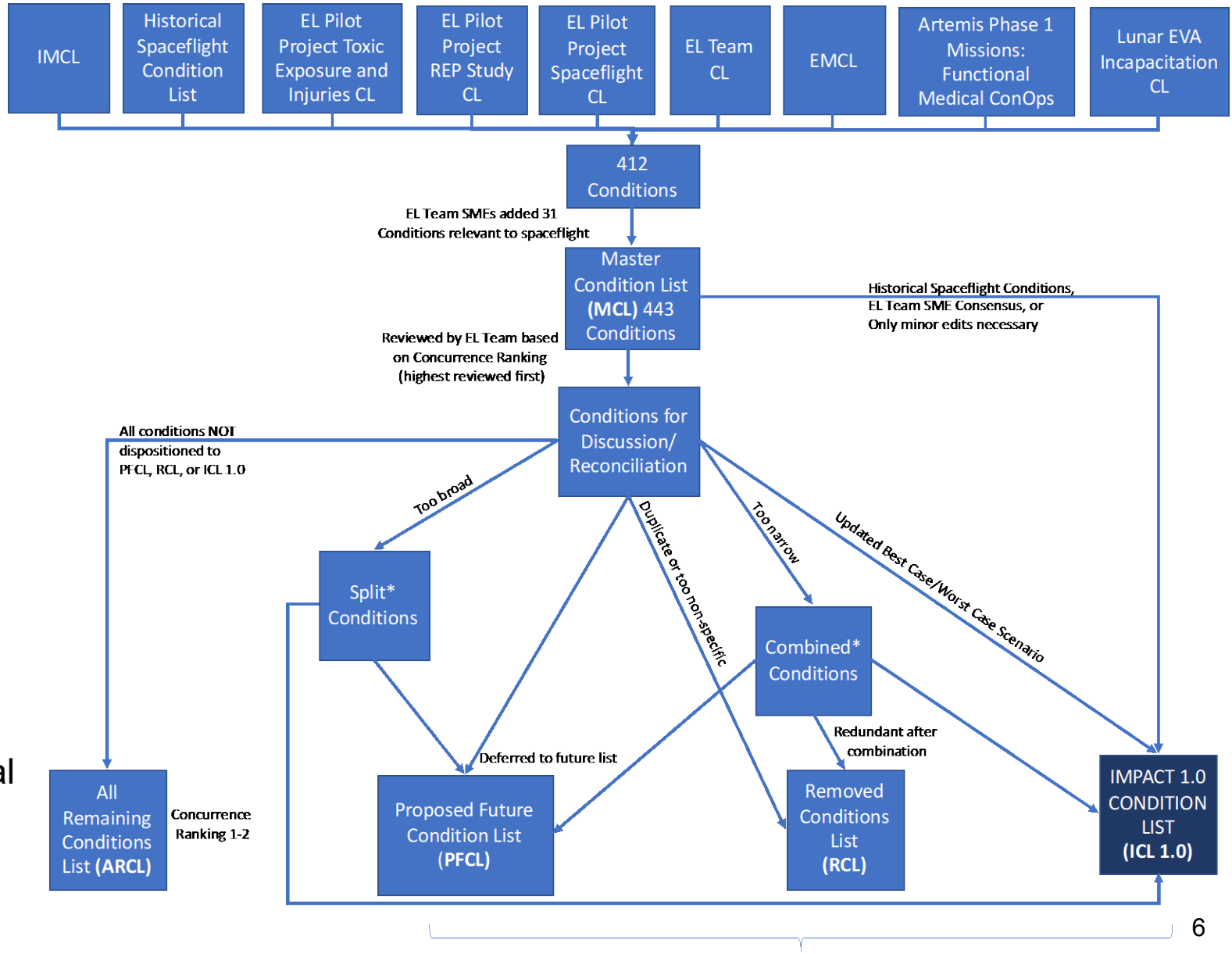
Example Outputs
- Medical risks
- Optimized medical kit contents
- Medical conditions treated/untreated
- Mission requirements met/unmet

Why Do We Need New Evidence for IMPACT?

Category	IMM	IMPACT
Medical Evidence & Conditions	Baselined to ISS/LEO	Baselined to exploration missions
Environment	Microgravity, lower radiation exposure	Partial gravity, gravity well, higher radiation risks, surface operations
Communications	Real-time	Significant time delays
Return to Earth	Within 1 day	Minimum 3 days (lunar) to months/years (Mars)
Resupply	Scheduled	May be impossible
Medical Decision Making & Expertise	Earth-based	Earth independent
Evidence data base	10 years old	Most recent, including spaceflight data

IMPACT v1.0 Medical Conditions List (ICL 1.0)

- **New/expanded condition list in comparison to IMM**
  - n=120 vs 100
  - Resource and schedule-feasible number to meet IMPACT v1.0 delivery at end of FY22
  - Expanded conditions for BHP, EVA, Gravity Well syndromes
- **Sourced from 9 different condition lists and 443 potential conditions**
- **Final list**
  - Medical conditions that occurred in spaceflight automatically included
  - Reviewed and agreed to by ExMC Clinical and Science Team, two SD Flight Surgeons, and a Physician-Astronaut



Medical Condition List Lessons Learned

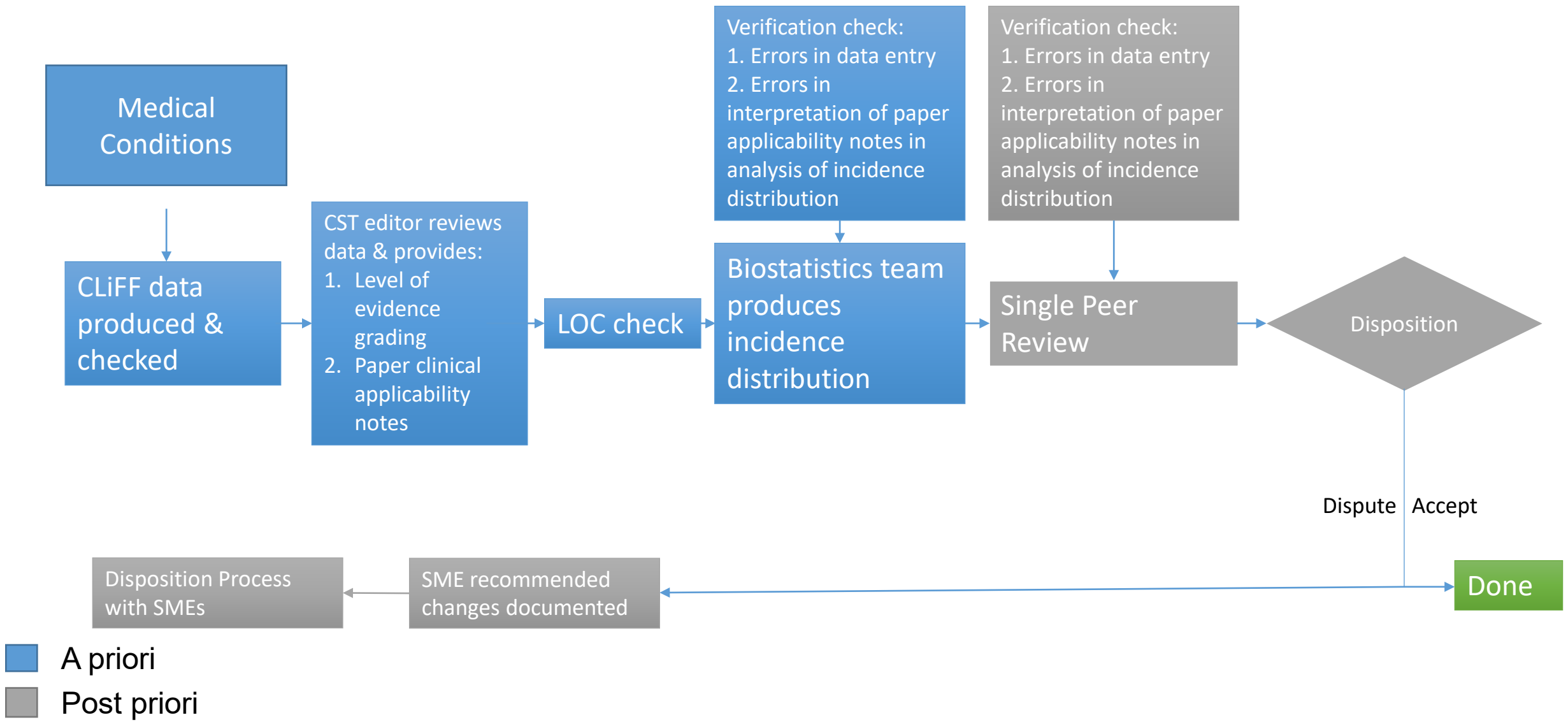
- **Spaceflight Medical Operational expertise should be consulted regarding the addition of future conditions.**
- **A clinician experienced with the nuances of spaceflight needs to have a minimum of 20 hours per condition to adequately source the evidence.**
- **Condition definitions should be carefully crafted to maintain mutual exclusivity and prevent overlap.**
- **Future inclusions for consideration as medical conditions**
  - Common side effects from medications
  - Common incidental findings in laboratory studies
  - Consequential side effects of diagnostic and procedural capabilities

CliFF Data – Wrist Fracture Example

TABLE 4. CLIFF TREATMENT & OUTCOME TABLE BY CLINICAL PHASE (Wrist Fracture CliFF)

Case Scenario	*Composite Incidence**	*Condition Probability^*	*CP1: Diagnosis*		*CP2: Treatment*			*CP3: Condition End State*				
			TI%	*Duration*	*TI%*	*Duration*		*TI%*	*RTDC*		*LOCL*	
			Preset	Preset	Preset	Min	Max	Preset	Min %	Max %	Min %	Max %
Treated Best Case (TBC)	Males: mean 0.0031 (SD: 0.00918) per surface EVA Females: mean 0.00831 (SD 0.0176) per surface EVA	61.02	100%	1.23	10.922	672	1512	0	3	6.7	0	0
Treated Worst Case (TWC)		38.98	100%	1.23	60.776	2160	8760	10.019	100	100	0	0
Untreated Best Case (UTBC)		*N/A*	*N/A*	2.07	28.568	672	1512	10.019	3	6.7	0	0
Untreated Worst Case (UTWC)		*N/A*	*N/A*	2.07	72.495	2160	8760	27.717	100	100	0	0

Development & Review of Clinical Finding Forms (CLiFFs)



Level of Confidence

- **Use of Level of Confidence (LOC)**
  - LOC grades evidence based on applicability of paper to the medical condition in the context of the spaceflight environment
  - NOT based solely on:
    - Research methodology
    - Source type (analog, terrestrial, spaceflight)
  - Scale of 0-4 that correlates to NASA-STD-7009
  - LOC graded for evidentiary sources as well as for the CliFF overall

LEVEL OF CONFIDENCE (LOC) SCORING
Articles obtained to update the evidence behind this CLiFF were scored by ExMC editors, based on their applicability to the Exploration Spaceflight environment using the following grading scale: 4 – Confident 3 – Somewhat confident 2 – Neutral 1 – Somewhat unconfident 0 – Not confident The following considerations factor into the grading scale above: • How closely does the paper describe the medical condition as defined by the IMPACT 1.0 Condiltion List (relevance)? • How closely does the population included resemble the astronaut population? • Quality of the paper (number of subjects, methods, etc.) • How much does the editor trust the source of the evidence? • How closely does the editor think that the data represents the exploration spaceflight environment? • Other considerations, at the discretion of the editor, supported in the comments for LOE scoring.

Return to Definitive Care

- Replaced “Evacuation” from IMM
- Implies going to a higher level of care (HLS to Gateway), possibly returning to earth but not necessarily
- However, in some scenarios (Mars) RTDC may not be possible for extended periods
- Initial evidentiary surrogates were “need for hospitalization” or “need for surgical care” but in some cases lead to unrealistically high rates of RTDC

Refinements

- **Dividing into lunar and deep space RTDC definitions**
  - **Scenarios where there may not be a near-term earth return capability are too difficult to combine with lunar missions where earth return is possible within 2 weeks**
  - **May need to develop separate evidence to support RTDC estimates for deep space missions**
- **Taking into account onboard capabilities**
  - **For some conditions inpatient capabilities and resources (e.g. IV antibiotics) may be present onboard**
- **Taking into account operational decisions (e.g., delaying shoulder surgery)**
  - **Mission objectives may require delaying medical procedures not available onboard**

Task Time Lost

- **Replaced IMM's "Functional Impairment" which was based on terrestrial AMA guidelines**
- **Determined by looking at total tasks on a DRM and what percentage would be impaired if a condition existed (TI%)**
- **TI% is multiplied by treatment time to calculate TTL**
- **Task impairment does not mean full impairment, just impairment of that task, also considers**
  - Would treatment (meds) impair the crew?
  - Would the condition cause aeromedical disqualification?
  - Would performing the task worsen the condition?
  - Would the associated pain impair other categories?

A Brief Word on the Task Impairment Process

				Criteria for Assignment of Conditions to Tas	Total Tasks Impaired By Condition	Total Human System Category Tasks Full	TI Decimal	TI %
	Assumptions: -Austere environment surgical capabilities including percutaneous options. -Open surgery ONLY available if there is NO ALTERNATIVE. Limited			3) Does the condition have a high likelihood of causing a significant aeromedical contraindication with an associated human system task categor 4) Would performing tasks in an associated task categor worsen the condition? (If so, it is affected). 5) Does pain associated with the condition impair ang further human system categories?				
					3763	3763	1	100
ICL1	ABDOMINAL WALL HERNIA	BEST CASE	Tx	Asymptomatic or mildly symptomatic hernia not requiring surgery.	211	3763	0.05607228	5.6072
			Utx	Asymptomatic or mildly symptomatic hernia not requiring surgery.	792	3763	0.21047037	21.047
		WORST CASE	Tx	Hernia requiring either non-emergent surgery or emergent surgery due to complications.	3763	3763	1	100
			Utx	Hernia requiring either non-emergent surgery or emergent surgery due to complications.	3763	3763	1	100

W Fernandez, D Levin, J Steller, E Kerstman, J Lemery, C Zahner, H Davis, K Lehnhardt, B Easter, A Kreykes. Task impairment: A novel approach for assessing impairment during exploration-class spaceflight missions. Journal of Space Safety Engineering, 2023.

Review of TI Process – Factors that Affect TI Values That May be Improved

1) TI is based on the (entire) Mars Task List

– Modify Mars Task List to be more DRM-specific (e.g., for lunar missions)

2) TI was performed *before* the treatment time (CP2 Durations) and capabilities and resources (CRTs) were developed

– Make the maximum treatment time (CP2) the end of the mission, instead of extending beyond mission duration

– Will require modifications in software that limit the maximum treatment time

3) TI only accounts for patient impairment (not CMO impairment)

– Create TI for CMOs

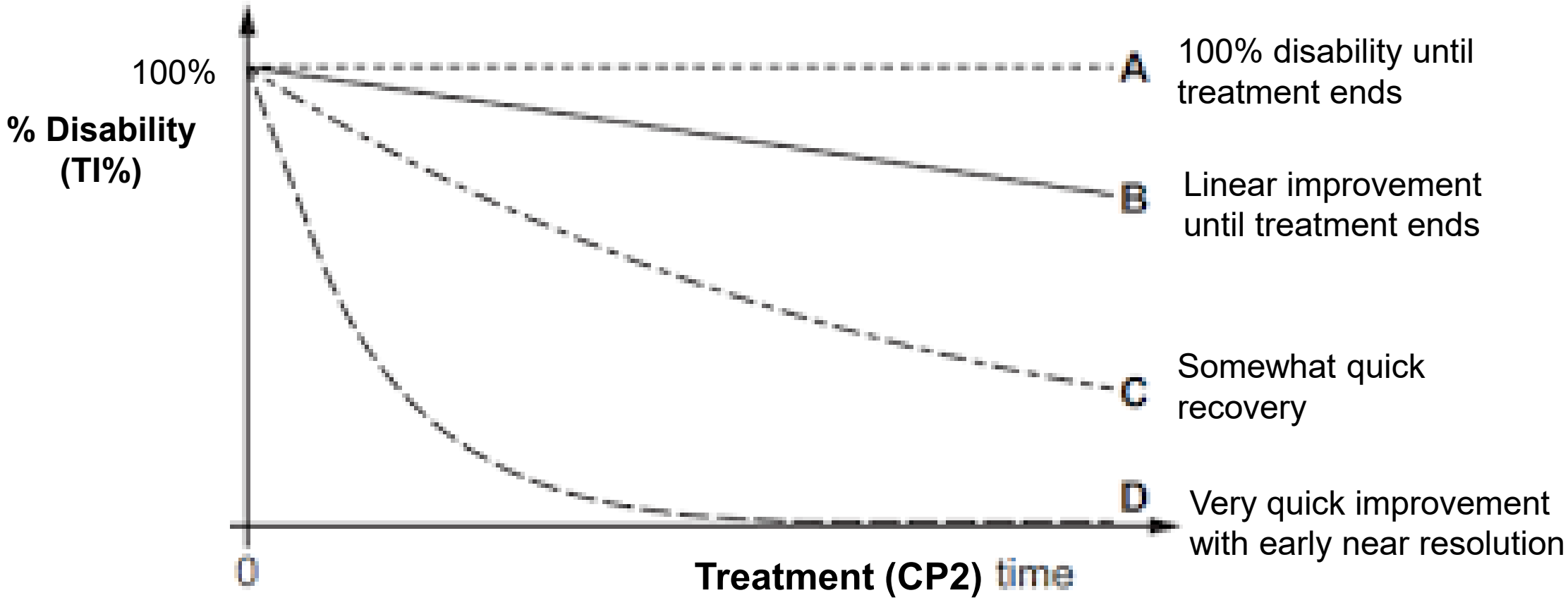
– Requires determination of CMO treatment times

4) Currently, model assumes that crewmember is 100% impaired throughout treatment time, does not account for improvement with time

-- Change TTL to reflect that affected crew will improve with ongoing treatment

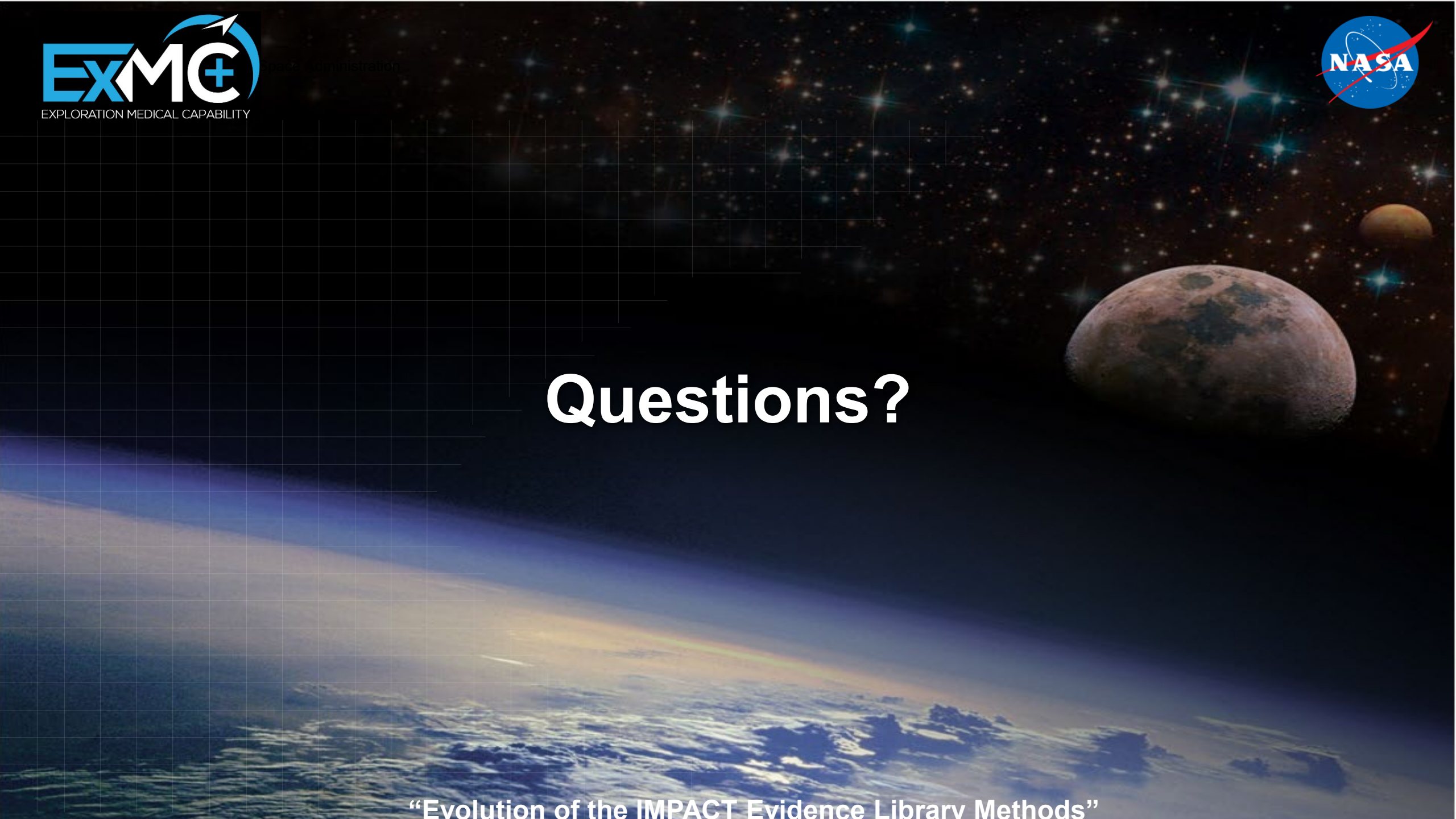
Examples of improvement in impairment curves with treatment

TTL = TI% x CP 2 time = AUC of Disability Function



Lessons Learned on Other Parameters

- **Incidence**
  - Spaceflight incidence, although based on small population sizes, is the gold standard.
  - Terrestrial incidence should be applied cautiously.
  - In some cases where marked improvement has occurred in equipment, better to use engineering PRA models (e.g., EVA hardware)
- **Best case/worst case**
  - Data informing this split is usually terrestrial.
  - Drives outcomes in the model and terrestrial data often overestimate severity of expected cases in spaceflight.
  - Should consider actual capabilities onboard
- **LOCL**
  - Terrestrial mortality data is difficult to apply to astronauts who, invariably, have fewer comorbidities than terrestrial subjects.
  - It must be applied judiciously.


EXMC
EXPLORATION MEDICAL CAPABILITY
NASA
Questions?
“Evolution of the IMPACT Evidence Library Methods”